

INTERVIEW SUMMARY

Examiner Sasan's grant of a personal interview on July 27, 2011, is gratefully acknowledged. Applicants' attorney, Ted Whitlock, attended the interview with Examiner Sasan, joined via teleconference by Dr. David Beach, acting on behalf of the applicant.

At issue during the interview were the rejections presented in the May 24, 2011 Office Action. In particular, the Hess reference (Swiss Patent document CH648754) was cited as an anticipating reference under 35 USC 102, and under 35 USC 103, in combination with US Pat. No. 4,786,547, to Schmidt, as making obvious the subject invention.

Applicants' attorney presented arguments to distinguish the subject invention from Hess and/or Schmidt. First, the subject invention concerns a tablet having a score on the bottom (active) segment or layer only, which neither reference describes. This "bottom-score-only" requirement was unexpectedly discovered in view of the further recognition that tamping the first (bottom) layer or segment cannot be carried out by an embossed top punch without disadvantageously forming an undesired indentation in the top surface of the bottom segment if tamped. Thus, the interface of the two segments is not level or planar, and does not provide a discrete separation of the segments. Prototype tablets and photographs illustrating these distinctions were shown to the Examiner.

In addition, Dr. Beach explained the inoperability of a tablet as described in the Hess reference. Inoperable features described by Hess include the perimeter band having a flat face, which can result in adherence or "twinning" of the tablets when coatings are applied as Hess describes. Hess further fails to describe tamping of the initial (bottom) layer, which can prevent the formation of a discrete interface between the layers and adequate formation of the active segments. Finally, scoring of the top layer is described in Hess, which requires an embossed top punch. A tamping step cannot be performed using an embossed top punch because an or indentation is formed in the first layer, which is filled in by the second layer, resulting in increased surface area at the break plane, which can alter the release profile of a controlled release or matrix tablet, as compared to its profile as a whole tablet.

Applicants' attorney agreed to provide amended claims consistent with these distinctions and to submit an expert declaration by Dr. Beach supporting the arguments.